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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,306	10/25/2001	Murali Nayudu	13377-002001	8939

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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,306	NAYUDU ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 28-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *24-27 and 73-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 24-27 and 73-102 as amended (12/02/2004) are under examination in the instant office action.

Claims 1-23 and 28-72 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as drawn to nonelected inventions.

Deposit

Deposit requirements for *Pseudomonas* strain AN5 rif (AGAL accession no. 00/09624) have been met in the response papers filed 12/01/2004.

Response to Arguments

Applicant's arguments filed 12/01/2004 have been fully considered but they are not persuasive for the reasons below.

Claim Rejections - 35 USC § 112

Indefinite

Claims 24-27 and 73-102 as amended are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is rendered indefinite by the phrase "a level comparable". The term "a comparable level" is a relative term that renders the claim indefinite. The term "a level comparable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "a level comparable" is not defined by the claim because it is uncertain as claimed whether "level" is better/worse or lower/higher than the level provided by the presently claimed strain AN5 rif.

Further, the specification does not and it cannot provide a standard for ascertaining the requisite degree because there is no other naturally occurring strains besides the parent strain AN5 and its naturally occurring mutant strain AN5 rif (page 68, lines 18-24) as disclosed. The other applicants' mutants are the genetically modified mutants (page 68 lines 25-31; page 69, lines 14-17; page 71, table 4). The genetically modified strains, if claimed, would belong to a different invention because they would encompass a totally different scope of subject matter belonging to a different class/subclass. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention as related to the instant claims. The scope of instant invention is drawn to naturally occurring strain(s) or to strain AN5 rif that is derived from parent strain AN5. Although the genetically modified strains might have been disclosed by applicants, they are not/have not been claimed and, thus, they are not/have not been examined. Besides, the genetically modified mutant are "comparable" to the parent strains AN5 but not to the claimed strain AN5 with regard to prevention of growth of fungal pathogen(s) or take-all disease as disclosed (table 4, page 71).

Claims 25-27 remains indefinite with regard to the phrase "derivatives" because it is uncertain as claimed and as disclosed what strains would be "derivatives" as intended and what characteristics the "derivatives" would have.

Claims 74, 88 and 98 are redundant and, thus, indefinite for failing to point out further limiting structural elements.

Claims 75, 89 and 99 remain indefinite with regard to the phrase "PQQ" or "cofactor PQQ" because it is uncertain what capacity are required to be expressed or what characteristics, properties are claimed.

Claim Rejections - 35 USC § 112

New matter

Claims as amended are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation drawn to derivatives "having the same or enhanced ability to reduce or prevent the growth of the fungus relative to said *Pseudomonas* strain AN5 rif (AGAL accession no. 00/09624)" (see claims 25-27) and to bacterial cells "comparable" to strain AN5 rif have no support in the as-filed specification.

The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples f the newly limited genus that would show possession of the concept of the "comparable" or "enhanced" mutants or derivatives from strain AN5 rif.

There is only one applicants' strain AN5 rif and the prior art strains AN5 and PF5 that possess anti-fungal activity and the other strains including AN5-MN1 and AN5-MN2 do not have significant anti-fungal activity as disclosed by applicants (page 55, lines 11-15). Thus, there

is no support for mutants with "same or enhanced ability" as presently claimed. The other mutant strains are "comparable" to parent AN5 but not to the strain AN5 rif (table 4, page 71). Thus, there is no support for any "comparable" mutants with "same or enhanced ability" as encompassed by the presently claimed invention.

This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of limitations drawn to derivatives "having the same or enhanced ability to reduce or prevent the growth of the fungus relative to said *Pseudomonas* strain AN5 rif (AGAL accession no. 00/09624)" (see claims 25-27) and to bacterial cells "comparable" to strain AN5 rif are considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 24-27, 73-80, 82-84, 86-94 and 96-102 are rejected under 35 U.S.C. 102(b) as anticipated by Nayudu et al. {IDS filed 1/07/2002, reference AP} or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nayudu et al. {IDS filed 1/07/2002, reference AP} for the reasons as explained in the prior office action and for the reasons below.

Claims are directed to an isolated biocontrol agent comprising bacterial cell(s) that belong to the genus of *Pseudomonas*, that are not the cells of the strain AN5, that produce sugar

acid when cultured on aldose sugar and that are capable to colonize sites of fungal plant pathogens. The claimed cell(s) has the biocontrol properties comparable to the strain AN5 rif such as ability to grow on an aldose sugar and to produce the sugar acid and the anti-fungal plant pathogen effects. Some claims are further drawn to the agent ability to convert glucose to glucuronic acid and to the agent anti-fungal effects towards *Gaeumannomyces graminis* (Gr or take-all fungus). Some claims are further drawn to methods for treating a fungal plant infection and for protecting a post-harvest plant product by applying the agent to the plant or to the plant post-harvest product.

The reference by Nayudu et al. discloses several mutants that derived from the parent strain AN5 and, thus, are not the cells of the strain AN5 within the meaning of the claims (page 122, col. 2, par. 1). These isolated mutants/derivatives are capable to utilize sugar such as glucose and, thus, to produce acid such as gluconic acid at least to the some degree as the parent strain AN5. These isolated mutants/derivatives are capable to produce biocontrol effects against fungal plant pathogens including fungus *Gaeumannomyces graminis* (Gr or take-all fungus) at least to the some degree as the parent strain. Therefore, the mutants/derivatives disclosed by the cited reference are reasonably expected to have identical properties as the "biocontrol properties" of the claimed strain AN5 rif because the presently claimed strain is also the mutant/derivative of the same parent strain AN5 as the disclosed mutants/derivatives. Thus, the cited reference anticipates the presently claimed composition comprising bacterial cells as claimed.

With respect to claims 75, 89 and 99 it is noted that although the cited reference is silent with regard to the " cofactor PQQ" capacity, the disclosed mutants/derivatives are reasonably expected to possess this ability at least to some degree because they are derivatives of the parent

strain AN5 that is disclosed as having the ability or genes as related to the claimed properties drawn to cofactor PQQ (see specification page 39, lines 25-31). Thus, the mutants/derivatives of the cited reference, that utilize glucose and produce anti-fungal effects, inherently contain at least some of the genes related to the PQQ within the meaning of the claims.

The cited reference also teaches method of treating fungal take-all *Gaeumannomyces graminis* Gr plant pathogen infection on the agar plates and in the plant-pot assays by using the isolated mutants/derivatives (page 12, col. 1, par. 3). The cited reference also teaches method of protecting post-harvest plant product such as plant seeds wherein the method comprises one active step of seed treatment with the isolated mutants/derivatives. Thus, the cited reference anticipates the presently claimed methods of using the claimed composition comprising bacterial cells as claimed.

Thus, the referenced microorganisms/methods of using microorganisms appear to be identical to the presently claimed microorganisms/methods of using microorganisms and are considered to anticipate the claimed invention.

In the alternative, even if the claimed microorganisms are not identical to the referenced strains with regard to some unidentified characteristics, for example: comparison with AN5 rif, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganisms are likely inherently possess the same characteristics of the claimed microorganisms particularly in view of the similar characteristics which they have been shown to share such as assignment to the same genus/species, ability to colonize infection site and at least some ability to reduce fungal pathogens. Thus, the claimed

microorganisms/methods of using microorganisms would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Therefore, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicants argue (response page 19 of 21) that the cited references teaches the "reduced antibiosis mutants" or the mutant that would not be "comparable" to characteristics of the applicants' strain AN5 rif. Nevertheless, the referenced microorganisms are said to have ability to colonize plants infected with pathogens and at least some anti-fungal activity. With respect to the "comparable" results or effects as related to AT5 rif, it is noted the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicant's strains differ and, if so, to what extent, from the strains discussed in the reference. Accordingly, it has been established that the prior art strains, which are of the same species as that claimed, likewise share the property of being able to inhibit plant fungal pathogens, and thus demonstrate a reasonable possibility that the compared strains are either identical or sufficiently similar; and therefore, the processes for treatment of plants whatever differences exist, are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence is shifted to Applicants. Applicants have not met that on the record.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 24-27 and 73-102 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over by Nayudu et al. {IDS filed 1/07/2002, reference AP} taken with Dahiya et al. {Bot. Bull. Academia Sinica (1988), 29: 135-142}, Scnider et al. {IDS filed 1/07/2002, reference AQ} and US 4,456,684 for the reasons as explained in the prior office action and repeated herein.

Claims 24-27, 73-80, 82-84, 86-94 and 96-102 as explained above. Some claims are further drawn to the agent ability to produce anti-fungal effects towards *Botrytis fabae.*

The reference by Nayudu et al. teaches bacterial agent or cells that clearly effective against plant pathogens including fungus *Gaeumannomyces graminis*. But it is missing disclosure with regard the anti-fungal effects towards *Botrytis fabae.*

However, the reference by Dahiya et al. demonstrates that bacterial cells belonging to *Pseudomonas* as the cells of the reference by Nayudu et al. are capable to produce pyrrolnitrin and phenazine antibiotics that are active against fungal plant pathogens belonging to *Gaeumannomyces* and to *Botrytis* (see abstract).

Further, the reference by Scnider et al. is relied upon to demonstrate that bacterial cells belonging to *Pseudomonas* as the cells of the references by Nayudu et al. and by Dahiya et al. produce various antibiotics active towards various plant pathogens, are capable to utilize glucose and possess genes related to the PQQ biosynthesis (page 3856, col. 1 and 2).

Furthermore, the cited US 4,456,684 is relied herein upon to demonstrate the anti-fungal protective amounts of *Pseudomonas* bacterial cells that are effective in the methods for treating fungal infections of plants and for protecting post-harvest plant products or seeds (col. 9, lines 46-50; col. 6, lines 59-61). Although the bacterial strains disclosed by US 4,456,684 are not

derived from the strain AN5 but they are isolated from soil, they are capable to utilize an aldose sugar glucose (col. 10, line 41) and to produce anti-fungal effects, and, thus, they are substantially similar, is not identical, to the presently claimed "derivatives" within the meaning of the claims.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain a biocontrol agent composition with bacterial cells belonging to *Pseudomonas* as encompassed by the presently claimed invention with a reasonable expectation of success in the possession of the agent intended for treating fungal plant pathogen infections including that belonging to *Gaeumannomyces* and to *Botrytis* because the bacterial cells belonging the *Pseudomonas* have been taught to produce antifungal effects towards the same group of plant pathogens as the presently claimed bacterial agent. The claimed characteristics as related to the PQQ manner or PQQ biosynthetic pathways have been known within the group of bacteria belonging to *Pseudomonas* that produce anti-fungal effects. The amounts of *Pseudomonas* bacterial cells that are effective for treating fungal plant pathogens have been taught in the prior art. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

With respect to the applicants' arguments drawn to "comparable" to AN5 rif results/effects, it is noted the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not all applicant's strains differ and, if so, to

what extent, from the strains discussed in the reference. Accordingly, it has been established that the prior art strains, which are of the same species as that claimed, likewise share the property of being able to inhibit plant fungal pathogens, and thus demonstrate a reasonable possibility that the compared strains are either identical or sufficiently similar; and therefore, the processes for treatment of plants whatever differences exist, are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence is shifted to Applicants. Applicants have not met that on the record.

With respect to claims 91 and 101 it is noted that these claims appear to be drawn solely to the use of applicants' novel and deposited strain *Pseudomonas* strain AN5 rif (AGAL accession no. 00/09624) and, therefore, claims 91 and 101 might be allowed, if presented in independent form.

No claims are allowed in the instant office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

February 18, 2005

V. Afremova

VERA AFREMOVA

PRIMARY EXAMINER